

REMARKS

A. BACKGROUND

The present Amendment is in response to the Office Action mailed December 4, 2008. Claims 2-10 were pending and rejected in view of cited art.¹ Claims 2 and 7 are amended. Claims 2-10 remain pending in view of the above amendments.²

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, is consistent with the Examiner's understanding.

B. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The Office Action rejected claim 7 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In response, Applicant has amended dependent claim 7, which Applicant believes more clearly defines the claimed invention. Applicant, therefore, respectfully requests withdrawal of the rejection under Section 112 in view of the included amendment.

¹ Although the prior art status of the cited art is not being challenged at this time, Applicant reserves the right to challenge the prior art status of the cited art at any appropriate time, should the need arise. Accordingly, any arguments and amendments made herein should not be construed as acquiescing to any prior art status of the cited art.

² Support for the claim amendments can be found throughout the specification and drawings as originally filed.

C. PRIOR ART REJECTIONS

I. REJECTION UNDER 35 U.S.C. § 103

The Office Action rejected claims 2, 3, 5, 8, 9, and 10 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,437,631 (*Janzen*) in view of U.S. Patent No. 6,517,569 (*Mikus*). Claims 4 and 7 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Janzen* in view of *Mikus* and further in view of U.S. Patent No. 5,593,412 (*Martinez*). Claim 6 was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Janzen* in view of *Mikus* and further in view of U.S. Patent No. 5,868,755 (*Kanner*)

Janzen was cited as disclosing "the claimed invention except for the skin separating from the outer surface of the elongate member as the closure element is advanced towards the distal end" (Office Action, Page 4). To overcome this deficiency, the Office Action cites *Mikus* for

"a skin or sleeve 20 overlying at least a portion of an outer surface between a closure element (30, 50) and a distal end of the elongate member (15) and wherein the skin separates or split from the outer surface of the elongate member from a proximal end of the skin toward a distal end of the skin when the closure element is advanced" (Office Action, Page 4).

Applicant respectfully disagrees with the characterization of *Mikus*. The skin or sleeve 20 identified in the Office Action is disposed within rather than disposed on the outer surface of the elongate member 15 and does not "separate[or split] from the outer surface of the elongate member." Further, the identified skin or sleeve of *Mikus* does not "separate[] from the outer surface of the elongate member as the closure element is advanced towards the distal end" as cited in independent claim 2. Rather, a distal end of the skin or sleeve separates during proximal movement of the outer sheath 15, and then, following distal displacement of "the distal portion of stent 50 from peel-away sheath 20", "[t]he clinician separates pull handles 24, tearing apart tab 26. The separated halves of peel-away sheath, having been 'peeled-away' from one another, may now be completely retracted from stent 50. Stent 50 does not proximally displace with this retraction because the already-deployed distal end of stent 50 anchors it" (Col. 5, ll. 64-65 and col. 6, ll. 35-41). As such, the skin or sleeve of *Mikus* appears to separate from the distal end first and then from the proximal end toward the distal end following deployment of the stent. As such, *Mikus* neither teaches nor suggests that "the skin separates from the outer surface of the elongate member as the closure element is advanced towards the distal end" as recited in independent claim 2. Consequently, even if *Mikus* was combined with *Janzen*, the combination would still neither teach nor suggest the invention claimed in independent claim 2.

In addition, even if, *arguendo*, *Mikus* teaches or suggests a skin as proposed by the Office Action, Applicant respectfully submits that there would be no reason to combine the skin or sleeve of *Mikus* with *Janzen*. During the procedure described in *Janzen*, “[w]hile slight forward pressure is maintained on the pusher 50 (see arrow A in FIG. 5), inner sheath 32 and sleeve 45 are slowly withdrawn (see arrow B in FIG. 6)” (Col. 5, ll. 43-45). Distal movement of the pusher 50 and slow withdrawal of the inner sheath 32 and sleeve 45 directs the hemostatic material distally from the sleeve 45 toward the arterial puncture. The sleeve 45 has to be sufficiently rigid to withstand the force applied by the pusher 50 to direct the hemostatic material to the arterial puncture so that “the hemostatic material 48 is left exposed to the blood in tissue channel 41, thereby activating the clotting action of the hemostatic material which quickly closes in around the front of sheath 32, sealing puncture 14 and producing hemostasis” (Col. 5, ll. 47-53). Inclusion of a separatable or splittable skin as described in *Mikus* on preloaded sleeve 45 would result in the hemostatic material following the course of least resistance through the separated or split skin rather than being directed distally to be delivered adjacent to the arterial puncture to close the puncture. This would render the modified device of *Janzen* unsatisfactory for its intended purpose of “sealing puncture 14 and producing hemostasis” (*See id.*).

Furthermore, there would be no reason to modify the coaxial cylinder 43b, identified in the Office Action as a skin or sleeve, because the location of sheath 32 relative to coaxial cylinder 43b would appear to prevent expansion of the skin or sleeve sufficiently to separate or split. Further, coaxial cylinder 43b is not disposed on the outer surface of the device as recited in independent claim 2, but rather disposed within both sheath 42 and preloaded sleeve 45.

In addition to there being no reason to include the separatable or splittable skin as described in *Mikus* with the preloaded sleeve 45, there would be no reason to include a separatable or splittable skin on the second sheath 42, which receives the preloaded sleeve 45. As illustrated, the second sheath 42 includes “an enlarged collar section 47 to limit the depth to which sheath 42 can be inserted into the wound. . . [and] a radiopaque band 44 at its distal end” (Col. 4, ll. 63-66). Because the enlarged collar section 47 and the radiopaque band 44 would prevent splitting or separation of the sheath 42 and there is no teaching or suggestion of splitting such collar or band, a splittable or separable sheath cannot be incorporated with the second sheath.

In addition to the above, *Janzen* was cited as disclosing “inserting a distal end of an actuator member (45, 43a) between the proximal end of the closure element (48) and the outer

surface of the elongate member (32) until the distal end of the actuator member is coupled with the closure element" (Office Action, page 3). The identified actuator member (45) is a "[p]reloaded sleeve 45 [that] has coaxial cylinders 43a and 43b which define an annular space 49 into which hemostatic material 48 is preloaded" (Col. 5, ll. 35-37). It does not appear, therefore, that "inserting . . . until the distal end of the actuator member is coupled with the closure element" occurs, because the hemostatic material (*arguendo*, the closure element) is already coupled to the actuator member before the preloaded "sleeve (45) is slid over the sheath (32)" (Col. 5, ln. 40). Therefore, Applicant respectfully submits that *Janzen* neither teaches nor suggests such a step as recited in independent claim 2.

With respect to "engaging tissue adjacent the distal end of the elongate member (32) with tissue engaging elements . . . on the closure element (48), Applicant notes that it appears that the Examiner is relying on personal knowledge as a basis for rejecting claims 2, 3, 5, 8, 9, and 10. Accordingly, and pursuant to 37 C.F.R. 1.104(d)(2), Applicant hereby respectfully requests an Examiner affidavit that: (i) specifically identifies any and all reference(s), other than those that have been specifically cited by the Examiner, upon which the obviousness rejection of the claims is based and (ii) provides complete details as to the reasoning and analysis of the Examiner concerning those references as those references are purported to apply to the rejection of the claims. This request applies to any and all claims rejected either in whole or in part based on Official Notice and/or upon assertions in the Office Action, such as those assertions related to the closure element being a hemostatic material and that the "engaging elements [of the closure element] are the parts of the material which interact with the blood to cause the clotting action" (Office Action, Page 3). Finally, please note that this request for an affidavit pursuant to 37 C.F.R. 1.104(d)(2) remains in force throughout the prosecution of this case unless expressly withdrawn by the Applicant.

Turning now to the rejection of claims 4 and 7 in view of *Janzen* in view of *Mikus* and further in view of *Martinez* and the rejection of claims 4 and 7 in view of *Janzen* in view of *Mikus* and further in view of *Kanner*, Applicant respectfully submit for at least the reasons identified above neither *Janzen* nor *Mikus*, whether individually or collectively, teach or suggest the invention of independent claim 2. Neither *Martinez* nor *Kanner* overcome the deficiencies of *Janzen* or *Mikus*. Consequently, Applicant respectfully requests withdrawal of the rejection of independent claim 2, and associated dependent claims 3-10, under Section 103 in view of *Janzen*, *Mikus*, *Martinez* or *Kanner*, whether collectively or individually.

D. CONCLUSION

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

Applicant also requests that the Examiner call the Applicant's representative, Fraser D. Roy, at telephone number (801) 533-9800 to schedule an in-person interview to discuss the response filed herein. Applicant's representative proposes Monday or Tuesday of either the week of April 12th or April 20th for such an in-person interview.

For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 4th day of March, 2009.

Respectfully submitted,

/Paul N. Taylor, Reg # 57271/

PAUL N. TAYLOR
Registration No. 57,271
Attorney for Applicant
Customer No. 057360
Telephone No. 801.533.9800

FDR: PNT: kdj
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